

WHAT IS CLAIMED IS:

1. An apparatus for analyzing a material sample, said apparatus comprising:  
an analyte detection system; and  
a sample element configured for operative engagement with said analyte detection system, said sample element comprising a sample chamber having an internal volume of less than 2 microliters;  
said analyte detection system including a processor and stored program instructions executable by said processor such that, when said material sample is positioned in said sample chamber and said sample element is operatively engaged with said analyte detection system, said system computes estimated concentrations of said analyte in said material sample with a standard error of less than about 30 mg/dL, with a 95% confidence level, when compared to corresponding actual concentrations of said analyte in said material sample.
2. The apparatus of Claim 1, wherein said standard error is less than about 20 mg/dL.
3. The apparatus of Claim 1, wherein said standard error is less than about 15 mg/dL.
4. The apparatus of Claim 1, wherein said standard error is less than about 10 mg/dL.
5. The apparatus of Claim 1, wherein said standard error is about 8.2 mg/dL.
6. The apparatus of Claim 1, wherein said standard error is between about 8.2 mg/dL and about 30 mg/dL.
7. The apparatus of Claim 1, wherein said analyte detection system comprises a source of electromagnetic radiation and a detector positioned to detect radiation emitted by said source, so that said source and said detector define an optical path therebetween.

8. The apparatus of Claim 7, wherein said sample chamber comprises at least one window which is transmissive of at least a portion of said electromagnetic radiation emitted by said source, and said window is located in said optical path when said sample element is in operative engagement with said analyte detection system.

9. An apparatus for analyzing a material sample, said apparatus comprising:

an analyte detection system; and

a sample element configured for operative engagement with said analyte detection system, said sample element comprising a sample chamber having an internal volume of less than 2 microliters;

said analyte detection system including a processor and stored program instructions executable by said processor such that, when said material sample is positioned in said sample chamber and said sample element is operatively engaged with said analyte detection system, said system computes estimated concentrations of said analyte in said material sample, said estimated concentrations deviating from corresponding actual concentrations of said analyte in said material sample by an RMS error of less than 30 mg/dL.

10. The apparatus of Claim 9, wherein said RMS error is less than 15 mg/dL.

11. The apparatus of Claim 9, wherein said wherein said RMS error is less than 10 mg/dL.

12. The apparatus of Claim 9, wherein said wherein said RMS error is about 8.0 mg/dL.

13. The apparatus of Claim 9, wherein said analyte detection system comprises a source of electromagnetic radiation and a detector positioned to detect radiation emitted by said source, so that said source and said detector define an optical path therebetween.

14. The apparatus of Claim 13, wherein said sample chamber comprises at least one window which is transmissive of at least a portion of said electromagnetic radiation emitted by said source, and said window is located in said optical path when said sample element is in operative engagement with said analyte detection system.

15. A system for estimating the concentration of an analyte in a material sample, said system comprising:

a source of electromagnetic radiation;

a detector positioned to detect radiation emitted by said source, so that said source and said detector define an optical path therebetween; and

a sample element configured to be positioned in said optical path, said sample element comprising a sample chamber at least partially defined by opposed first and second windows which are substantially transmissive of at least a portion of the radiation emitted by said source and which define an optical pathlength through said sample element, said sample chamber having an internal volume of less than 2 microliters;

wherein, when said material sample is positioned in said sample chamber and said sample chamber is positioned in said optical path, said system computes estimated concentrations of said analyte in said material sample with a standard error of less than about 30 mg/dL, with a 95% confidence level, when compared to corresponding actual concentrations of said analyte in said material sample.

16. The system of Claim 15, wherein said standard error is less than about 20 mg/dL.

17. The system of Claim 15, wherein said standard error is less than about 15 mg/dL.

18. The system of Claim 15, wherein said standard error is less than about 10 mg/dL.

19. The system of Claim 15, wherein said standard error is about 8.2 mg/dL.
20. The system of Claim 15, wherein said standard error is between about 8.2 mg/dL and about 30 mg/dL.
21. A system for estimating the concentration of an analyte in a material sample, said system comprising:
- a source of electromagnetic radiation;
  - a detector positioned to detect radiation emitted by said source, so that said source and said detector define an optical path therebetween; and
  - a sample element configured to be positioned in said optical path, said sample element comprising a sample chamber at least partially defined by opposed first and second windows which are substantially transmissive of at least a portion of the radiation emitted by said source and which define an optical pathlength through said sample element, said sample chamber having an internal volume of less than 2 microliters;
- wherein, when said material sample is positioned in said sample chamber and said sample chamber is positioned in said optical path, said system computes estimated concentrations of said analyte in said material sample, said estimated concentrations deviating from corresponding actual concentrations of said analyte in said material sample by an RMS error of less than about 30 mg/dL.
22. The system of Claim 21, wherein said RMS error is less than about 20 mg/dL.
23. The system of Claim 21, wherein said wherein said RMS error is less than 15 mg/dL.
24. The system of Claim 21, wherein said wherein said RMS error is less than about 10 mg/dL.
25. The system of Claim 21, wherein said wherein said RMS error is about 8.2 mg/dL.

26. A system for estimating the concentration of an analyte in a material sample, said system comprising:

a source of electromagnetic radiation;

a detector positioned to detect radiation emitted by said source, so that said source and said detector define an optical path therebetween;

a sample element configured to be positioned in said optical path, said sample element comprising a sample chamber at least partially defined by at least one window which is substantially transmissive of at least a portion of the radiation emitted by said source;

a processor in communication with said detector; and

stored program instructions executable by said processor such that, when said window deviates from planarity by more than one micron, and when said material sample is positioned in said sample chamber and said sample chamber is positioned in said optical path, said system computes an estimated concentration of said analyte in said material sample with clinically sufficient accuracy.

27. The system of Claim 26, wherein said system computes said estimated concentration with clinically sufficient accuracy when said window deviates from planarity by more than two microns.

28. The system of Claim 26, wherein said system computes said estimated concentration with clinically sufficient accuracy when said window deviates from planarity by more than four microns.

29. The system of Claim 26, wherein said system computes said estimated concentration with clinically sufficient accuracy when said window deviates from planarity by about eight microns.

30. The system of Claim 26, wherein said system computes said estimated concentration with clinically sufficient accuracy when said window deviates from planarity by between about one micron and about eight microns.

31. The system of Claim 26, wherein clinically sufficient accuracy comprises sufficient accuracy to meet requirements imposed by relevant regulatory authorities and/or medical practitioners.

32. The system of Claim 26, wherein clinically sufficient accuracy comprises sufficient accuracy to provide a satisfactory diagnostic result for device users.

33. A method of facilitating measurement of glucose concentration in human blood, said method comprising:

providing a plurality of 1,000 or more sample elements, each of said sample elements comprising a sample chamber at least partially defined by first and second walls, at least one of said walls being configured to be substantially transmissive of at least a portion of an analysis beam of electromagnetic radiation, said walls defining an optical pathlength through said sample element;

said plurality of sample elements having substantially uniform external dimensions and substantially uniform sample chamber volumes across the plurality while being characterized by a standard deviation in optical pathlength of more than about 0.256 microns.

34. The method of Claim 33, further comprising employing at least a portion of said plurality of sample elements with an analyte detection system to compute estimated concentrations of glucose in human blood with clinically acceptable accuracy.

35. The system of Claim 34, wherein clinically acceptable accuracy comprises sufficient accuracy to meet requirements imposed by relevant regulatory authorities and/or medical practitioners.

36. The system of Claim 34, wherein clinically acceptable accuracy comprises sufficient accuracy to provide a satisfactory diagnostic result for device users.

37. A method of measuring the concentration of glucose in human blood, said method comprising:

providing a sample element comprising a sample chamber at least partially defined by first and second walls, at least one of said walls being configured to be substantially transmissive of at least a portion of an analysis beam of electromagnetic radiation, said walls defining an optical pathlength through said sample element, said optical pathlength deviating from an expected optical pathlength by more than 1 micron; and

employing said sample element to compute said concentration of glucose in human blood with clinically acceptable accuracy.

38. The method of Claim 37, wherein said optical pathlength deviates from said expected optical pathlength by more than 2 microns.

39. The method of Claim 37, wherein said optical pathlength deviates from said expected optical pathlength by more than 4 microns.

40. The method of Claim 37, wherein said optical pathlength deviates from said expected optical pathlength by more than 8 microns.

41. The method of Claim 37, wherein said optical pathlength deviates from said expected optical pathlength by about 10 microns.

42. The method of Claim 37, wherein said optical pathlength deviates from said expected optical pathlength by between about 1 micron and about 10 microns.

43. The system of Claim 37, wherein clinically acceptable accuracy comprises sufficient accuracy to meet requirements imposed by relevant regulatory authorities and/or medical practitioners.

44. The system of Claim 37, wherein clinically acceptable accuracy comprises sufficient accuracy to provide a satisfactory diagnostic result for device users.

45. A system for estimating the concentration of an analyte in a material sample, said system comprising:

a source of infrared radiation;

a detector positioned to detect infrared radiation emitted by said source, so that said source and said detector define an optical path therebetween;

a sample element configured to be positioned in said optical path, said sample element comprising a sample chamber at least partially defined by opposed first and second windows which are at least partially transmissive of infrared radiation and which define an optical pathlength through said sample element;

a processor in communication with said detector; and

stored program instructions executable by said processor such that, when said optical pathlength deviates from an expected optical pathlength by more than 1 micron and when said material sample is positioned in said sample chamber and said sample chamber is positioned in said optical path, said system computes an estimated concentration of said analyte in said material sample with clinically acceptable accuracy.

46. The system of Claim 45, wherein said system computes said estimated concentration with clinically acceptable accuracy when said optical pathlength deviates from said expected optical pathlength by more than two microns.

47. The system of Claim 45, wherein said system computes said estimated concentration with clinically acceptable accuracy when said optical pathlength deviates from said expected optical pathlength by more than four microns.

48. The system of Claim 45, wherein said system computes said estimated concentration with clinically acceptable accuracy when said optical pathlength deviates from said expected optical pathlength by more than eight microns.



49. The system of Claim 45, wherein said system computes said estimated concentration with clinically acceptable accuracy when said optical pathlength deviates from said expected optical pathlength by about ten microns.

50. The system of Claim 45, wherein said system computes said estimated concentration with clinically acceptable accuracy when said optical pathlength deviates from said expected optical pathlength by between about one micron and about ten microns.

51. The system of Claim 45, wherein clinically acceptable accuracy comprises sufficient accuracy to meet requirements imposed by relevant regulatory authorities and/or medical practitioners.

52. The system of Claim 45, wherein clinically acceptable accuracy comprises sufficient accuracy to provide a satisfactory diagnostic result for device users.

53. A method of determining the concentration of an analyte in a bodily fluid, the method comprising:

- providing a plurality of 20 or more sample elements, each of said sample elements comprising a sample chamber at least partially defined by first and second walls, at least one of said walls being configured to be substantially transmissive of at least a portion of an analysis beam of electromagnetic radiation, said walls defining an optical pathlength through said sample chamber;

- selecting a first sample element from said plurality of sample elements;

- placing a first sample of bodily fluid in the sample chamber of said first sample element;

- positioning said first sample element, with said first sample disposed therein, in an analyte detection system comprising a source of electromagnetic radiation, so that a beam of radiation emitted by said source can pass through said first sample;

- operating said analyte detection system to determine the concentration of said analyte in said first sample with clinically sufficient accuracy;

selecting a second sample element from said plurality of sample elements, the optical pathlength of said second sample element differing from the optical pathlength of said first sample element by more than one micron;

placing a second sample of bodily fluid in the sample chamber of said second sample element;

positioning said second sample element, with said second sample disposed therein, in said analyte detection system so that a beam of radiation emitted by said source can pass through said second sample;

operating said analyte detection system to determine the concentration of said analyte in said second sample with clinically sufficient accuracy, and without need to communicate said second pathlength to said analyte detection system.

54. The method of Claim 53, wherein operating said analyte detection system to determine the concentration of said analyte in said second sample comprises operating said analyte detection system without need to communicate said first pathlength to said analyte detection system.

55. The method of Claim 53, wherein operating said analyte detection system to determine the concentration of said analyte in said second sample comprises operating said analyte detection system without need to communicate any difference between said first pathlength and said second pathlength to said analyte detection system.

56. The method of Claim 53, wherein operating said analyte detection system to determine the concentration of said analyte in said second sample comprises operating said analyte detection system without communicating said second pathlength to said analyte detection system.

57. The system of Claim 53, wherein clinically sufficient accuracy comprises sufficient accuracy to meet requirements imposed by relevant regulatory authorities and/or medical practitioners.

58. The system of Claim 53, wherein clinically sufficient accuracy comprises sufficient accuracy to provide a satisfactory diagnostic result for device users.